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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,024	12/05/2000	David Bisaro	22727/04080	3134

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EXAMINER	
HELMER, GEORGIA L 13	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,024	BISARO, DAVID	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-6,10,11,14-16,19,21,22 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-9,12,13,17,18,20 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No. 9, filed 1 October 2002. Claims 1-24 are pending. Applicant elects Group II claims 7-20 and 23, directed to isolated, double domain recombinant AL2 genes and to methods of making recombinant plants, and further elects (A) Deletions, and (1) a plurality of cysteine residues, without traverse. Elected claims 15, 16 and 19 are dependent on Group I claims, and properly belong with Group I claims. Group II claims 10, 11 and 14 are drawn to non elected inventions. Claims 7-9, 12, 13, 17, 18, 20 and 23 are examined in this action. Claims 1-6, 10, 11, 14, 15, 16, 19, 21, 22 and 24 are withdrawn as belonging to non-elected inventions. This restriction is made FINAL.

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 3, filed 16 February 2001, is attached to the instant Office action.

Claim Rejections - 35 USC § 112-second

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 7-9, 12, 13, 17, 18, 20 and 23 are rejected under 35 U.S.C. 112-2nd.

In claim 7,

- "double domain" is unclear—does this mean comprising two domains? If so, what constitutes a domain?
- "AL2" is unclear; is this an acronym? The full name and meaning needs to be recited at least once. If this is an geminivirus gene, that should be recited in the claim.
- "modified" is unclear because this can mean any change, from a single amino acid to total deletions, for example. The metes and bounds of this term is not clear.
- from "about amino acid 83 to about amino acid 129" is indefinite because the metes and bounds of "about" are undefined. Does about 83 mean 84? Or 89? All subsequent recitations of this language are also rejected, including in claim 8.
- The frame of reference for the amino acid numbers 83 and 129, 23 and 43, is not given. Without a standard these numbers are meaningless. All subsequent recitations of this language are also rejected.
- "Gene" is unclear because a "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant's intention, the language "a DNA of interest" is suggested. Or Applicant may recite the various components of the "gene" desired. All subsequent recitations of this language are also rejected.
- "a second mutation" implies a first mutation, but none is recited.

In claim 8, "said first mutation" lacks antecedent basis.

In claim 9,

- a comparison is made with a corresponding wild-type transcription activator protein. However, it is unclear what constitutes the wild-type protein. Therefore, it is unclear what would constitute a protein having one to 20 fewer amino acids.

In claim 13,

- "plurality" is not clear. What does this mean in the context of this claim?
- what is "the central region"?
- what is the "corresponding wild-type transcription activator protein"?

Clarification/correction is required..

Claim Rejections - 35 USC § 112, first paragraph

Written description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 7-9, 12, 13, 17, 18, 20 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7 is drawn to a double domain recombinant AL2 gene encoding a modified transcription activator protein comprising a mutation in the region which encodes from about amino acid 83 to about amino acid 129 and a second mutation in the region which encodes from about amino acid 23 to about amino acid 43 of said transcription activator protein. There is no structural description of what comprises the modified transcription activator protein. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

Claim 8 is drawn the recombinant AL2 gene of claim 7 wherein the encoding a modified transcription activator protein comprising a first mutation in the region which encodes from about amino acid 115 to about amino acid 129. There is no structural description of what comprises the modified transcription activator protein. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

Claim 9 is drawn the recombinant AL2 gene of claim 7 wherein the first mutation is a deletion and the mutant gene has from one to 20 fewer amino acids than the corresponding wild-type. There is no structural description of what comprises the modified transcription activator protein. Neither the size of the gene nor that of the corresponding protein able to defined. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

Claim 12 is drawn the recombinant AL2 gene of claim 7 wherein the second mutation is a deletion and the mutant gene has from one to 20 fewer amino acids than

the corresponding wild-type. There is no structural description of what comprises the modified transcription activator protein. Neither the size of the gene nor that of the corresponding protein able to defined. Nor is any description given of what the corresponding wild-type protein is. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

Claim 13 is drawn the recombinant AL2 gene of claim 7 wherein the second mutation is a substitution in which a plurality of the cysteine residues are substituted. There is no structural description of what comprises the modified transcription activator protein. Neither the size of the gene nor that of the corresponding protein is able to defined. Since the extent of the substitution is not given, the size of the resulting gene and protein cannot be described. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

There is no structural description of what comprises the modified transcription activator protein. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application

was filed. (see Written Description Requirement published in Federal Register/Vol.66; No. 4/ Friday, January 5, 2001/Notices; p. 1099-1111.)

Claim Rejections - 35 USC § 112-Enablement

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 7-9, 12, 13, 17, 18, 20 and 23 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The enablement issues are *(i)* the double domain recombinant AL2 gene(s) encoding modified transcription activator protein comprising various mutations, and *(ii)* a method of preparing a transgenic plant comprising vectors comprising these genes. Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)). The Wands factors are

- the nature of the invention,
- the state of the art,
- the predictability or lack thereof in the art,
- the amount of guidance given,
- the presence of working examples,
- the quantity of experimentation necessary,

- the relative skill in the art, and
- the breadth of the claims.

The claims are drawn to double domain recombinant AL2 gene encoding a modified transcription activator protein comprising a mutation in the region which encodes from about amino acid 83 to about amino acid 129 and a second mutation in the region which encodes from about amino acid 23 to about amino acid 43 of said transcription activator protein; to a first mutation in the region which encodes from about amino acid 115 to about amino acid 129; where the first mutation is a deletion and the mutant gene has from one to 20 fewer amino acids than the corresponding wild-type; and wherein the second mutation is a deletion and the mutant gene has from one to 20 fewer amino acids than the corresponding wild-type. The claims are also drawn to a method of preparing a transgenic plant, comprising transforming a sample of a plant which is host for a Begomovirus with the vectors comprising the claimed inventions (see supra) and generating a plants from the transformed sample.

The state of the art and the predictability or lack thereof: The state of the art is such that one of skill in the art can readily make DNA constructs, clone virus genes and make mutants. However, one skilled in the art cannot make transcription activator protein genes having specific mutations and groups of mutations which function as transcription activator protein without guidance as to which sites, which mutations, which deletions, and of what size, and which combinations of mutations will function as desired. Applicant has provided no guidance on how to predictably eliminate

inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

Guidance and presence of working examples: Applicant describes generally how to construct double domain genes having the desired characteristics, but does not teach specific mutations or give SEQ ID Nos for such constructs. Applicant claims mutations without reciting specific regions and specific domains, another problems is that Applicant recites changes re "the corresponding wild-type transcription activator protein" without defining what the wild-type transcription activator protein is. Since the double domain genes are not exemplified, the method of preparing a transgenic plant by using them is not enabled.

In view of the breadth of the claims (any AL2 gene, any modified transcription activator protein, any mutation, any deletion, any central region, and any Begomovirus), the lack of guidance in the specification, the lack of working examples, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 7-9, 12, 13, 17, 18, 20 and 23 are rejected under USC 102 (b) over applicant's admitted state of prior art.

Applicant's admitted state of the prior art teaches the amino acid sequences of Figure 1, which are aligned AL2 sequences of various geminiviruses. The amino acid sequence of SEQ ID NO: 1, a TGMV protein, is aligned with SEQ ID NO: 2, of AbMV. SEQ ID NO: 1 is identical to the AL2 gene of TGMV, taught by Hamilton, et. al. , EMBO J. 3, 2197-2205, 1984. SEQ ID NO: 2 is identical to the AL2 gene of AbMV, taught by Wu, et al, (Complete nucleotide sequence of a non-vector transmissible strain of abutilon mosaic geminivirus, 1996, Phytopathology 86, pages 608-613). The amino acid sequences of Figure 1, are aligned AL2 sequences of various geminiviruses. The amino acid sequence of the TGMV AL2 protein, as aligned with the AL2 protein of AbMV is clearly mutant one with the other at the regions from about amino acid 83 to about 129 and at about amino acid 23 to about 43.

Accordingly, Applicant's admitted prior art anticipates the claimed invention.

Remarks

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service, whose telephone number is 703-308-0196.

Georgia Helmer PhD
Patent Examiner
Art Group 1638
March 23, 2003

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600